UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337
THIS DOCUMENT RELATES TO:	
United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 09-CV-10547	Hon. Patti B. Saris
United States ex rel Ven-A-Care of the Florida Keys, Inc.v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 00-10698	

COMMONWEALTH OF MASSACHUSETTS' SUR-REPLY MEMORANDUM IN OPPOSITION TO JOINT MOTION FOR APPROVAL OF SETTLEMENT BETWEEN CALIFORNIA, FLORIDA AND VEN-A-CARE AND THE SCHERING/WARRICK DEFENDANTS

INTRODUCTION

In their 29-page Reply Memorandum the Schering/Warrick defendants fail to meet their burden of explaining why their flawed Settlement Agreement should be approved by this Court. Even if the Attorney General's refusal to consent to the voluntary dismissal of the pending *qui tam* actions is subject to judicial review, the Schering/Warrick defendants have utterly failed to demonstrate that the Attorney General's position is arbitrary and capricious. The Schering/Warrick defendants fail to address, let alone rebut, the critical fact that there are no "adverse litigants" in this case, with regard to the advisory opinions they seek. The

Schering/Warrick defendants also fail to recognize that Massachusetts is not suing on behalf of the United States and that any resolution they reach, by verdict or settlement, with the United States or with Ven-A-Care, will not resolve their liability under the Massachusetts False Claims Act. Contrary to their assertions, the 193-page report that the Schering/Warrick defendants have submitted in connection with their Reply Memorandum demonstrates the inadequacy, not the adequacy, of their $55 million proposed settlement amount.

ARGUMENT

I. The Attorney General's Refusal To Consent Is Not Arbitrary or Capricious.

The Schering/Warrick defendants assert that the Attorney General's refusal to consent to the voluntary dismissal of these *qui tam* actions is reviewable by this Court under the arbitrary and capricious standard. Reply In Support of Motion for Approval of the Settlement Agreement, Dkt.No. 6485 ("Reply Memo") at 4 and 12. Assuming, *arguendo*, that such review is proper, the Schering/Warrick defendants have utterly failed to demonstrate that the Attorney General's refusal to consent to voluntary dismissal is arbitrary or capricious.

"The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the [Attorney General.]" Motor Vehicle Mfgrs Assn. of the U.S. Inc v. State Farm Mutual Auto Ins. Co., 463 U.S.29, 43, 103 S.Ct. 2856, 2866 (1983). "A court should not set aside [the Attorney General's] actions as arbitrary and capricious unless the actions lack rational basis." Adams v. U.S. Environment Protection Agency, 38 F.3d 43, 49 (1st Cir. 1994).

There is ample evidence that the Attorney General's refusal to consent to the voluntary dismissal of these *qui tam* actions has a rational basis. The release of 22 additional Warrick generic drugs and 29 Schering brand drugs, beyond the Warrick albuterol drugs at issue in these

cases, is a rational basis to withhold consent. U.S. Memo in Opposition To Proposed Settlement Agreement, Dkt. No. 6414 ("U.S. Opposition") at 10-11. Similarly, conditioning the Settlement Agreement on the Court making advisory opinion findings of fact regarding, among other things, whether any of the WACs or AWPs for the Schering brand drugs were "misleading, deceptive or unfair" is a rational basis for withholding consent. Id. at 6-10. Given that the United States is expected to recover only $23.47 million, with regard to $292 million in federal reimbursement for Warrick albuterol drugs, in the still litigating states alone, and that this Court has found in the MDL trial that the spreads on those drugs during the relevant period ranged from 100% to 800%, this also provides a rational basis for the Attorney General to withhold his consent. Id. at 12-15.

II. The Schering/Warrick Defendants Have Failed To Demonstrate That Any of the "Findings" They Seek Would Be Found In The Context of An Actual Dispute Between Adverse Litigants.

In the Commonwealth's Opposition To Approval of the Settlement Agreement, the Commonwealth argued that the proposed "findings," on which the Schering/Warrick defendants have conditioned the Settlement Agreement, "are nothing less than advisory opinions." Dkt. No. 6457, p.7("Commonwealth's Opposition"). The Commonwealth cited case law demonstrating that in order for there to be a justiciable case, capable of resolution in an Article III court, there must be "an actual dispute between adverse litigants." Id. The Schering/Warrick defendants in their Reply Memorandum have totally failed to respond to these cases or address the issue, which their counsel has admitted, that Ven-A-Care and the Schering/Warrick defendants are "on the same side" as to these proposed findings. Transcript, 7/24/09 Hearing, 19:3. The single paragraph in their Reply Memorandum devoted to the "advisory opinion" issue does not address the issue of whether there are any "adverse litigants" with regard to the proposed "findings" in

this case. Reply Memo, Dkt. No. 6485, p.26. Similarly, the Reply Memoorandum does not address the Commonwealth's position that the presence of objectors to the Settlement Agreement, such as the Commonwealth, does not create the adversarial dispute required for an Article III case or controversy. Compare Commonwealth's Oppostion, Dkt. No. 6457, p.8 with Reply Memo, Dkt. No. 6485, p.26.

III. The Settlement Agreement, If Approved, Would Have No Preclusive Effect On The Massachusetts False Claims Act Action.

The Schering/Warrick defendants argue that a settlement of these federal *qui tam* actions would have a preclusive effect with regard to the Commonwealth's civil action against them. Reply Memo at 24. They assert, incorrectly, that "[i]n effect, this is a 'classic' situation where two cases are filed seeking the exact same dollars." Id. This argument mischaracterizes the federal and MA cases and ignores the law of issue and claim preclusion.

The federal and the Massachusetts actions are not two cases seeking the same dollars. The federal *qui tam* actions allege violation of the federal False Claims Act (FCA). The federal FCA provides that a person who violates the act "is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 … plus 3 times the amount of damages which the Government sustained because of the act of that person." 31 U.S.C. §3729(a). The federal cases seek to enforce the federal FCA, collect the civil penalties provided for in the statute and treble the damages the federal Government has incurred. The Massachusetts civil action, on the other hand, alleges violation of the Massachusetts FCA, among other causes of action. A person who violates the Massachusetts FCA "shall be liable to the commonwealth … for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth … sustains because of the act of that person," Mass. G.L. ch.12 §5B. The Massachusetts case seeks

to enforce the Massachusetts FCA, collect the civil penalties provided for in the statute and treble the damages which the Commonwealth has incurred.

The fact that Massachusetts has a statutory obligation to share a portion of its recovery with the federal government in no way limits what Massachusetts can recover under its false claims act. The Schering/Warrick defendants, in their price reporting practices, violated the laws of both sovereigns, and they are liable to both sovereigns for civil penalties and treble damages. A release of the federal claims in the federal *qui tam* actions does not preclude Massachusetts from recovering all the penalties and damages it is entitled to collect under its false claims act. If the Schering/Warrick defendants pay the federal government money which is attributable to the Warrick albuterol drugs in Massachusetts during the relevant time period, they will get credit for such compensatory payments, after the treble damages have been calculated. United States v. Bornstein, 423 U.S. 303, 314, 96 S. Ct. 523, 530 (1976) ("the Government's damages should be double before any compensatory payments are deducted.")

Claim preclusion under federal law has three ingredients: a final decision in the first suit; a dispute arising from the same transaction (identified by its "operative facts"); and the same litigants (directly or through privity of interest). U.S. ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849, 851 (7th Cir. 2009)[internal citations omitted]. The preclusive effect of a federal court judgment is determined by federal common law. Taylor v. Sturgell,--U.S.--, 128 S.Ct. 2161, 2171, 171 L.Ed.2d 155 (2008) . "It is a principle of general application in Anglo-American jurisprudence that one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process." *Id.* at 2166-67(quoting Hansberry v. Lee, 311 U.S. 32, 40, 61 S.Ct. 115 L.Ed. 22 (1940)).

The only authority the Schering/Warrick defendants cite in support of their preclusion argument is Giragosian v. Ryan, 547 F.3d 59 (1st Cir. 2008). Their reliance upon Giragosian is misplaced. In Giragosian, one plaintiff filed separate civil actions in state and federal courts alleging violation of his constitutional rights in connection with the revocation of his license to carry and sell firearms. 547 F.3d at 62. The state court action was decided first, adversely to the plaintiff. Id. The defendants argued in the federal action that the state court judgment was *res judicata* and precluded recovery. Id. The federal district court agreed and dismissed the action. Id. at 63. Applying the Massachusetts law of *res judicata*, the First Circuit affirmed, holding that the plaintiff "voluntarily proceeded in both forums, he is now subject to the consequences of claim preclusion." Id. at 65.

The Schering/Warrick defendants quote from Giragosian out of context. Reply Memo, p.24 ("[W]hen two actions are pending which are based on the same claims, or which involve the same issue, it is the final judgment first rendered in one of the actions which becomes conclusive in the other action.") This is true only when there is an "identity or privity of the parties to the present and prior actions." Giragosian, 547 F.3d at 63. In Giragosian, the same plaintiff brought both lawsuits. Thus, the issue was whether the two lawsuits arose from the same transaction. The court found that they did, so the judgment in the first action precluded the second action. Conversely, here, the plaintiffs in the two cases are different and there is no privity of interest. The Commonwealth is not a party in the federal *qui tam* actions and is not in privity with any party in the federal *qui tam* actions.

Defendants insist preclusion should apply because Massachusetts may pay some portion of its recovery to the federal government. However, the federal government is not a party in the Commonwealth's case, nor is it in privity with the Commonwealth. Something more is required

for privity than a mere common interest in the outcome. New Hampshire Motor Transport Ass'n v. Town of Plaistow, 67 F.3d 326, 328 (1st Cir. 1995). Non-party preclusion may apply if the nonparty vicariously participates in the litigation by exerting "substantial control" over the prosecution or defense of the case. Gonzalez v. Banco Cent. Corp., 27 F.3d 751, 757-58 (1st Cir. 1994). "Substantial control" is defined as the power to "call the shots." Id.; see also Montana v. United States, 440 U.S. 147, 153 (1979) (holding that non-party preclusion was appropriate because the Government had a sufficient "laboring oar" in the state court litigation: the Government stipulated that it "exercised control" over the litigation, required that the case be filed, reviewed and approved the complaint, and paid the attorneys' fees and costs); U.S. v. Sutherland, 929 F.2d 765, 771-72 (1st Cir. 1991) (holding that federal prosecutors were not precluded from litigating admissibility of tape recordings (which were previously barred in state court action) because there was no evidence that federal prosecutors played a role in or directly influenced the state court proceeding).

The Commonwealth has not exerted control over the federal *qui tam* actions, has not "called the shots," and has not bore the "laboring oar" in the litigation. There simply is no justification or factual basis for finding privity between the Commonwealth and Ven-A-Care or the federal government in connection to the federal *qui tam* cases. There is no identity of parties, thus there can be no claim preclusion.

The Schering/Warrick defendants also assert that the Commonwealth has failed to rebut their arguments that the release in their Proposed Order "would have preclusive effect" in the Commonwealth's case. Reply Memo, Dkt. No. 6485 at 24-25. In alleged support of this assertion they cite to their Joint Memorandum in Support of the Settlement Agreement, Dkt. No. 6360 ("Jt. Memo"). Id. at 25. Yet a review of those pages in their Joint Memorandum shows only legal

argument as to why a settlement by Ven-A-Care should have preclusive effect on the United States. There is no discussion there, or anywhere else in any of Schering/Warrick's filings, as to why a release by Ven-a-Care should have preclusive effect on the Commonwealth or why the Commonwealth should be deemed to be in privity with Ven-A-Care or the United States for claim preclusion purposes.

IV. The Settlement Amount Is Inadequate.

In alleged support of the adequacy of the Settlement Amount, the Schering/Warrick defendants submit the report of Paul F. Charnetzki, a CPA. Dkt. No. 6486 ("Charnetzki Report"). Mr. Charnetzki acted at the direction of Schering/Warrick's counsel and made assumptions at counsel's direction which are unduly favorable to Schering/Warrick. Notwithstanding these assumptions, Mr.Charnetzki still found that Schering/Warrick's single damages exposure, for the federal share only, for the 17 states and the NY localities still litigating with Schering/Warrick, was between $26.2 million and $32.1 million. Charnetzki Report at 4. Although Mr. Charnetzki did not do the calculation in his report, given that the federal FCA provides for civil penalties, plus mandatory trebling of damages, Schering/Warrick's federal exposure, based on the Charnetzki report, even given its assumptions, is a civil penalty of between $5,500 and $10,500 for every false claim submitted, plus damages of between $78.6 million and $96.3 million. Thus, it is misleading to suggest that DOJ cannot reasonably expect to recover more than $32.1 million in damages for the federal share. Reply Memo, pp.18-19.

The assumptions underlying the Charnetzki report are inappropriately generous to Schering /Warrick. First, he limited his calculations to the states and local entities that are still litigating with Schering/Warrick. Charnetzki Report, p.3 and App.3. The pending Ven-A-Care

qui tam cases are nationwide and relate to federal losses in all 50 states. Even assuming the federal government released its claims regarding the states which have settled with Schering/Warrick, which may be true only for the Texas settlement, there is absolutely no reason why federal damages related to the 23 states which never sued Schering/Warrick should not be included in the exposure calculation. No one disputes that the applicable penalties and treble damages attributable to those states are recoverable in the pending Ven-A-Care *qui tam* cases.

Second, Charnetzki excluded from his exposure calculation all reimbursement on a Warrick generic drugs after a Federal Upper Limit (FUL) was established for the drug. Charnetzki Report, ¶2.3, p.3. The only explanation for this assumption is footnote 13 in Schering/Warrick's Reply Memo, Dkt. No. 6485 at 21, which asserts "once CMS decided to set a FUL for a particular NDC, there cannot be future damages for that NDC." Schering/Warrick then cites to the transcript of the FUL tutorial hearing relating to CMS exercising discretion in setting FULs. Id. There is no explanation why CMS' exercise of discretion, even if true, would prevent damages as to an NDC. This assumption ignores the fact that FULs are *upper limit prices*. They set the maximum a state can pay, not what it would have paid if Warrick had reported truthful prices. State Medicaid programs reimbursed on the basis of the lowest of usually four prices, including the Estimated Acquisition Cost (EAC), which was usually calculated on the basis of prices Schering/Warrick reported to First DataBank. In Massachusetts in July, 2002 only 7% of pharmacy claims were paid based on the FUL, while 58% of claims were paid on the basis of EAC. Report to the General Court, 10/2/02, Dkt. No. 453-38 at 4. Notwithstanding the existence of a FUL, if the Schering/Warrick defendants had reported true prices in July, 2002 Massachusetts would have paid a lower EAC amount on 58% of the Warrick claims processed. Given the fact that virtually all of the Warrick drugs had FULs during the

relevant time, this assumption results in a gross underestimate of Schering/Warrick's damages exposure.

Third, Charnetzki assumed that in order to meet access requirements state Medicaid programs would need to have paid in excess of 250% or 300% of AMP. Charnetzki Report, ¶2.5. p.3. These percentage multipliers come from reports by the Office of the Inspector General (OIG) and the Government Accountability Office (GAO) relating to implementation of statutory changes in establishing FULs and certain pending legislative proposals to change the formula for FULs. Reply Memo, pp. 19-21. Schering/Warrick's assumption is that the Medicaid programs would have had to pay more than 250% of AMP to cover a pharmacy's acquisition cost. Id. at 20. However in the reports on which the assumption is based there is direct evidence that rebates, discounts and chargebacks were not included in the calculation of estimated pharmacy acquisition costs. The GAO report used IMS Health data, which was voluntarily provided by manufacturers and distributors to IMS Health. 12/22/06 GAO Report, Medicaid Outpatient Prescription Drugs: Estimated 2007 FULs for Reimbursement Compared with Retail Pharmacy Acquisition Costs at 3. The GAO acknowledged that the IMS Health data "do not account for rebates that pharmacies may receive from wholesalers or manufacturers." Id. The OIG Report used acquisition data provided by five wholesalers and distributors. June 2007 OIG Report, Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program at 8. Only 2 of the 5 distributors provided any discount or rebate information. Id. Even as to those two distributors, the OIG, presumably, did not capture data relating to discounts and rebates provided directly by the manufacturers. Given the magnitude of discounting with regard to generic drugs, there are serious questions whether the estimates of pharmacy acquisition costs in

either report are accurate or that state Medicaid programs would have to pay the assumed prices to maintain pharmacy participation.

The Schering/Warrick defendants concede there are "a number of other perspectives from which to evaluate the fairness, adequacy, and reasonableness of the settlement." Reply Memo at 21. They caution, however, that likely damages in these other scenarios would need to be discounted for "litigation risks." Id. In addressing litigation risk, however, they never acknowledge that this Court has already found, in the MDL trial:

- Schering and Warrick never lowered their reported AWPs despite offering significant discounts that reduced the ASPs. 491 F. Supp.2d 20, 70 (D. Mass. 2007).

- Schering and Warrick were well aware of the role that spread played in driving purchasing decisions for their products. Id. at 71.

- the spread on every Warrick albuterol NDC in every year were all over 100%, reaching 800% in 2003. Id. at 75.

Based on these finding the Court concluded

> Schering-Plough's subsidiary Warrick acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for its generic drug albuterol sulfate, which had mega-spreads between 100% and 800% throughout the class period. Id. at 31.

Given these findings there is good reason not to deeply discount for litigation risk.

The Schering/Warrick defendants completely ignore the fact that FCA violations mandate civil penalties and treble damages. They assert that defendants rarely pay 100% of damages to settle a case. Reply Memo at 22. This assertion ignores their experience in Missouri. The Schering/Warrick defendants went to trial; the jury returned a $9 million compensatory damages verdict. While the jury was deliberating punitive damages Schering/Warrick settled for $31 million, which is 3.44 times the single damages. It was a wise decision, as the jury later indicated it would have returned a $100 million punitive damages award.

CONCLUSION

For the foregoing reasons, and those contained in the Commonwealth's Opposition, Dkt. No. 6457, the Court should reject the Settlement Agreement and withhold its consent to the voluntary dismissal it contemplates. If Schering/Warrick wants to finally resolve all of its AWP liability, the Commonwealth and the other plaintiffs, stand ready to engage in good faith, realistic settlement discussions.

Respectfully submitted,

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Dated: September 11, 2009

Certificate of Service

I hereby certify I have caused a copy of the foregoing Sur-Reply Memorandum to be served on counsel for each other party in these actions by filing it electronically in the Court's CM/ECF system, this 11th day of September, 2009.

/s/Peter A. Mullin
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